

REMARKS

This Response addresses the issues raised by the Examiner in the Office Action mailed February 10, 2005. Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 3-13 are pending in the application, with claims 3, 10, 12, and 13 being the independent claims. These changes are believed to introduce no new matter, and their entry is respectfully requested. Support for the claim amendments can be found throughout the specification and claims as originally filed, and specifically on pages 3-6 and figures 1-4.

At the suggestion of the Examiner, claims 3-11 have been amended to recite a "kit."

The above Amendment places the claims in condition for allowance and if necessary, in better form for consideration on appeal and therefore, should be entered.

Based upon the above Amendment and the following Remarks, the Applicants respectfully request the Examiner reconsider all outstanding rejections and that they be withdrawn.

Rejection under 35 U.S.C. §112, 1st paragraph:

The claimed invention is enabled by the specification, such that one of ordinary skill in the art would know how to use the claimed invention, the device, without undue experimentation.

Claims 3-11 stand rejected under 35 U.S.C. §112, 1st paragraph, for failing to comply with the enablement requirement. Citing *Enzo Biochem Inc. v. Calgene, Inc.*, (CAFC, 1999) 52 USPQ2d at 1135, the Examiner alleges that the instant specification has not taught one skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. The Examiner asserts that the specification does not set forth starting materials and reaction conditions to the full extent of the claims' scope without having to resort to undue experimentation. The Examiner further states that the claimed invention relates to performing nucleic acid hybridization reactions as well as amplification reactions. The Examiner also points out various factors affecting hybridization reactions, which support his contention that the invention has not enabled the full scope of the hybridization reactions without undue experimentation.

Applicants respectfully request reconsideration and withdrawal of this rejection in view of the Amendments and Remarks set forth below. Contrary to the Examiner's view of the instant invention, the claims are enabled by the specification and do not require undue

experimentation. Applicants disagree with the Examiner's characterization of the invention. The claims that are now pending are directed to a kit and a device, which can be used to conduct hybridization reactions. The specific materials and hybridization conditions would be determined by each individual user of the device, such that the user obtains the desired results. Thus, the invention is directed to a mechanical tool that can be used to carryout hybridization assays.

Regarding how to make the claimed invention, it is well settled that as long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. §112 is satisfied. In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). Failure to disclose the other methods by which the claimed invention may be made does not render a claim invalid under 35 U.S.C. §112. Spectra-Physics, Inc. v. Coherent, Inc., 827 F.2d 1524, 1533, 3 USPQ2d 1737, 1743 (Fed.Cir.), cert. denied, 484 U.S. 954 (1987). The instant specification sets forth in detail how to make the claimed device (see pages 3-4). The drawings also set forth a fully illustrated preferred embodiment of the device. The preferred dimensions of the device are clearly stated in the first paragraph of page 4 of the specification. Therefore, since the specification sets forth how to make the claimed device and provides drawings of the preferred embodiments, the invention is enabled.

Regarding how to use the invention, it is also well settled that if a statement of utility in the specification contains within it a connotation of how to use, and/or the art recognizes that standard modes of administration are known and contemplated, 35 U.S.C. §112 is satisfied. In re Johnson, 282 F.2d 370, 373, 127 USPQ 216, 219 (CCPA 1960); In re Hitchings, 342 F.2d 80, 87, 144 USPQ 637, 643 (CCPA 1965). See also In re Brana, 51 F.2d 1560, 1566, 34 USPQ2d 1437, 1441 (Fed. Cir. 1993). The instant specification on page 2 teaches the dropping of a sample solution containing a sample biopolymer on a cover glass; and placing a slide glass having a probe biopolymer fixed thereon on the cover glass with fixed probe biopolymer facing down. The Applicants see nothing undue about the rather simple act of dropping a sample of biopolymer on a cover glass to be covered by a slide glass containing a probe biopolymer. Requiring the Applicants to discuss the details of the chemical properties of the sample solutions and the probe sequences is not only beyond the requirements of the law, but also unnecessary and unreasonable since the user of the device will determine the appropriate starting materials and reaction conditions.

Although the numerous factors for hybridization set forth by the Examiner may be important for using the device, they are not critical for enabling one of ordinary skill in the art to make and use the claimed device without undue experimentation. In other patents relating to a hybridization device and a method for detecting a hybridization reaction, which has the same assignee as the instant application, the claims were deemed definite despite the lack of details as to the "starting materials" or "reaction conditions." See U.S. 6,589,740 and U.S. 6,482,640. The patented device and method for detecting a hybridization reaction were independent of their use, such that the "starting materials" or "reaction conditions" were not necessary or critical for one of ordinary skill in the art to make and use the claimed invention, which is the same situation here.

Applicants believe that a skilled artisan, on the basis of what is taught in the specification, and what is known in the art at the time of filing the application, can make and use, without undue experimentation, the device of the present invention to carry out hybridization assays.

Rejection under 35 U.S.C. §112, 2nd paragraph:

The claimed invention is definite and the claims properly set forth the elements of the device, as well as the relationship of the individual elements that make up the device.

Claims 3-11 stand rejected under 35 U.S.C. §112, 2nd paragraph, as being indefinite for omitting essential cooperative relationships of elements that amount to a gap between the necessary structural connections. Specifically, the Examiner asserts that there is no structural connection between the cap, the cases, the film and the tray. The Examiner further notes that the language inserted by the applicants defining the functionality of the "sheet" (claim 3), and the tray (claim 10), did not cure the issue of the claim not reciting any structural connections between the various elements. The Examiner also points out that if structural connections in fact do not exist, to consider having claims drawn to a "kit," which can be comprised of various non-connected elements or components.

Applicants would like to thank the Examiner for the claim suggestion and note that claims 3-11 have been amended to recite a "kit." As such, the rejection as it applies to claims 3-11 is rendered moot. Applicants have added new claims 12 and 13 directed to a device. The new claims more clearly describe the cooperative relationship and structural connections

between the elements of the claimed device and as such, the rejection cited for claims 3-11 would also not apply to the newly added claims.

Applicants respectfully request reconsideration and withdrawal of this rejection in view of the Amendments and Remarks set forth below.

Contrary to the Examiner's view and characterization of the invention, the instant invention provides the structural connections between the various parts of the device. The cooperative relationship between the elements of the device is set forth such that gaps do not exist between the necessary structural connections. The claimed device is composed of a tray, a sheet, a case, and a cap. These elements provide for the make-up of the device, which can be used to conduct hybridization reactions.

Applicants do not share the Examiner's specialized meaning of a "device" and a "kit." By implication, the Examiner purports to define a "device" as an "assembled kit" because the so called "structural connectedness" test would be met by an assembled kit. Applicants are not aware that "structural connectedness" is a judicially imposed test for a device. What Applicants believe, however, is that claim terms would be construed along the lines of their plain and ordinary meaning in light of the specification. Further, being their own lexicographers, if the specification warrants a departure from the plain and ordinary meaning of a term, then such departure is required for proper construction of the claims.

Where words in a patent claim have no specialized meaning to persons of skill in the art, the ordinary meaning of those words to those skilled in the art control the construction of the words, unless the evidence indicates that the inventor used them differently. Karlin Technology, Inc. v. Surgical Dynamics, Inc., 177 F.3d 968 (Fed. Cir. 1999).

In terms of plain and ordinary meaning, the English dictionary defines a device as "that which is formed or invented for a specific use." Similarly, a kit is defined as "a set or collection of tools or other objects for a special purpose." *See Webster Dictionary of English Language*. Applicants believe that the instant invention, directed to a device for conducting hybridization reactions is more consistent with the plain and ordinary meaning of "device," than the Examiner's "structural connectedness" test. A hybridization device would necessarily contain at least two separate components—the probe container and the sample container—to be contacted for hybridization test.

Whereas the Examiner sees the cap, the cases, the films, and the tray, as separate and distinct tools more appropriately comprising a kit, Applicants have elected to describe them as embodiments of the instant device for conducting hybridization and related tests. In

particular, a hybridization kit would encompass not only the device of this invention, but also the droppers, probe readers, probe labels, reagents, sample preparation kit and so on necessary to carry out hybridization reactions. Even then, rarely are the so-called devices ever used by themselves. For instance, at what point does the detachable cap of a water bottle convert the bottle from a water-containing device to a water-containing kit? Is the Examiner contending that the cap even if specially made for that bottle, must always be affixed to the bottle whether or not there is water in the bottle in order to meet the test for a device? Applicants believe that the "structural connectedness" test for the Examiner's notion of a device applies only when the device is in use for the specific purpose for which it was made. In that sense, Applicants argue that the embodiments of the instant hybridization device are structurally and functionally connected when in use.

With respect to the alleged omission of essential structural cooperative relationships of elements, Applicant's respectfully contend that the Examiner's basis of that assertion, namely, the erroneous construction of the claim elements, has been traversed by the foregoing. Even then, a tray provided with a hollow for placing a slide glass defines a structural relationship. A sheet for fixedly placing a cover glass onto an inner bottom of the tray in the hollow defines another structural relationship. Further, a case for accommodating the tray therein and a cap for sealing the tray within the case define yet another structural relationship. Applicants are not aware of what the Examiner asserts to be missing in the mind of one skilled in the art in terms of how the different embodiments of this invention cooperate with each other.

If by structural relationship, the Examiner is insisting that all the embodiments must be mechanically linked prior to use in order for this device to be properly construed as a device, Applicants respectfully disagree with that notion and instead argue that even if the structural connectedness test of the Examiner were correct, the fact that all the embodiments of this invention are structurally linked while in use accords with the generally accepted meaning of that term. And to the extent that the usage of the term "device" in the claims is consistent with their understood meaning in the specification, Applicants have met the requirements of 35 U.S.C. § 112, 2nd paragraph.

However, to expedite the examination of this application and in no way acquiescing to the Examiner's arguments, the Applicants have herewith amended claims 3-11 to claim a "hybridization kit" as suggested in the outstanding Office Action.

Therefore, Applicants respectfully request reconsideration and withdrawal of this rejection in view of the Amendments and Remarks set forth above.

Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicant(s) therefore respectfully request(s) that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Response is respectfully requested.

Respectfully submitted,

Stanley P. Fisher
Registration Number 24,344



Juan Carlos A. Marquez
Registration No. 34,072

Toni-Junell Herbert
Registration No. 34,348

REED SMITH LLP
3110 Fairview Park Drive
Suite 1400
Falls Church, Virginia 22042
(703) 641-4200
April 11, 2005
SPF/JCM/TH